

# Exhibit 3

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

**IN RE: VALSARTAN PRODUCTS  
LIABILITY LITIGATION**

**CIVIL ACTION NUMBER:**

**1:19-md-02875-RBK-JS**

**ORAL OPINION DECIDING THE  
PARTIES' "MACRO" ISSUES  
LISTED IN THE OCTOBER 22,  
2019 ORDER  
(DOCUMENT NO. 280)**

Mitchell H. Cohen Building & U.S. Courthouse  
4th & Cooper Streets  
Camden, New Jersey 08101  
Wednesday, November 20, 2019  
Commencing at 2:12 p.m.

**B E F O R E:**

**THE HONORABLE JOEL SCHNEIDER,  
UNITED STATES MAGISTRATE JUDGE**

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1 THE DEPUTY CLERK: All rise.

2 (OPEN COURT; 2:12 p.m.)

3 THE COURT: Please be seated, counsel.

4 Okay. So, what the Court is going to do, it's going  
5 to read into the record its oral opinion ruling on all of the  
6 issues from today.

7 I'm going to confirm all of the rulings in an order  
8 which I hopefully will enter before the end of the week. In  
9 terms of the Court's oral opinion, the way it's organized is  
10 I'm just going to start out with some background and discuss  
11 some general issues, and then the meat of it is, obviously,  
12 the rulings on each specific issue.

13 So I thank the parties for their excellent briefs and  
14 argument. I hope I'm right that staging discovery this way  
15 helps advance the ball getting a decision, I hope, on the  
16 big-picture issues will help in your meet and confer sessions  
17 that are going to be ongoing in next few days. So here goes.

18 Presently before the Court to decide are what the  
19 Court has denominated macro discovery disputes. Although the  
20 term is not contained in the Federal Rules of Civil Procedure  
21 and is not normally part of a litigator's lexicon, the Court  
22 directed the parties to identify and brief important discovery  
23 disputes which are identified in the Court's October 21, 2019  
24 order.

25 The term refers to big-picture discovery issues that

1 overarch the scope of relevant discovery. Experience has  
2 shown that the prompt identification and rulings on these  
3 disputes goes a long way towards effectively and efficiently  
4 managing the discovery process, especially in complex  
5 litigation like this MDL. The Court's rulings are a necessary  
6 precedent to deciding the more granular discovery disputes  
7 the Court will address and decide on December 11, 2019.

8 At the moment, the Court is just addressing discovery  
9 disputes between plaintiffs and the API and finished dose  
10 manufacturing defendants. The current API manufacturing  
11 defendants participating in the case are ZHP and Mylan.  
12 Aurobindo and Hetero have not yet been served pursuant to The  
13 Hague Convention, or if they have been served, they have not  
14 entered an appearance.

15 The finished dose manufacturers currently  
16 participating in the case, and I'm not providing the exact  
17 precise technical corporate name, are Aurolife or Aurobindo,  
18 Teva and Torrent.

19 The parties are obviously familiar with the  
20 background of this matter, so only a short summary will be  
21 provided.

22 This MDL arises out of contamination discovered in  
23 defendants' Valsartan medication in July 2018. Plaintiffs  
24 generally contend the contamination contained cancer-causing  
25 chemicals that has or will cause personal injuries, such as

1 cancer and liver damage, as well as economic losses.

2 Defendants do not deny their Valsartan was contaminated but  
3 denied the contamination caused any injuries or damages.

4 The parties dispute important issues, such as the  
5 start date of the contamination, whether only the API was  
6 contaminated, the entire list of contaminating chemicals, and  
7 the facilities where the contamination occurred or should have  
8 been discovered.

9 The defendants in the case include manufacturers of  
10 the active pharmaceutical ingredient, or API manufacturers,  
11 finished dose manufacturers, wholesalers, distributors,  
12 repackagers and pharmacies. As noted, the discovery disputes  
13 to be addressed by the Court today only pertain to the API and  
14 finished dose manufacturers. Some of these parties are  
15 located in China and India. Macro and granular discovery  
16 disputes concerning the other categories of defendants will be  
17 addressed at a future date.

18 Plaintiffs' claims in the case have been grouped in  
19 the general categories that are reflected in the three filed  
20 master Complaints. The first master Complaint addresses the  
21 claims of individual plaintiffs who generally allege they  
22 contracted various forms of cancer from consuming defendants'  
23 contaminated Valsartan. To date, in excess of 125 personal  
24 injury cases of this type have been filed. Plaintiffs'  
25 counsel estimates approximately or perhaps 2,000 cases may

1 eventually be filed.

2           The second master Complaint is a nationwide medical  
3 monitoring class action filed on behalf of all "individuals  
4 who consumed contaminated generic Valsartan-containing drugs  
5 at least since January 1, 2012."

6           The potential class size is undoubtedly in the tens  
7 of thousands.

8           The third master Complaint is a nationwide economic  
9 class action filed on behalf of "all individuals and entities  
10 who since at least January 1, 2012, to the present, paid any  
11 amount of money for a Valsartan-containing drug."

12           Before it gets to the specific issues in dispute, the  
13 Court will address the general legal parameters that guide its  
14 rulings. The parties, of course, know the scope of relevant  
15 discovery is set forth in Rule 26(b)(1). Parties may obtain  
16 discovery of non-privileged information relevant to any  
17 party's claim or defense that is proportional to the needs of  
18 the case.

19           Although this MDL is or is likely to be massive in  
20 scope in terms of the number of potential claimants and the  
21 amount in controversy, the Court will not disregard the  
22 necessity of proportionality when it comes to deciding the  
23 discovery plaintiffs will be permitted to take.

24           The fact that this MDL is likely to involve thousands  
25 of potential claimants and disputes over hundreds of millions

1 of dollars is no reason to approve duplicative, unnecessary,  
2 cumulative, and unduly burdensome discovery.

3 On the other hand, when it evaluates the  
4 proportionality of plaintiffs' discovery requests, the Court  
5 cannot ignore the fact that hundreds of millions of dollars,  
6 perhaps even a billion dollars, may be in dispute.

7 The Court also cannot ignore the fact that Valsartan  
8 was and is a very popular high blood pressure medication  
9 perhaps taken by millions of people and that serious health  
10 concerns have been raised, although not yet proven, about the  
11 present and future health effects resulting from taking  
12 contaminated Valsartan.

13 It is beyond dispute that the public has a keen  
14 interest in the results of this litigation, and the issues in  
15 dispute are undoubtedly important to the public health and  
16 welfare. In addition, it is just as apparent that plaintiffs  
17 do not have access to the relevant information they need to  
18 prove their case, and that key information, such as when and  
19 how the Valsartan contamination occurred is within defendants'  
20 exclusive possession. These are relevant factors Rule 26  
21 directs this Court to consider in its proportionality  
22 analysis.

23 The Court also wants to make a few general  
24 observations about the parties' discovery disputes so it does  
25 not have to repeat itself when it separately addresses each



1 dispute. As a general matter, the Court agrees that  
2 plaintiffs' discovery requests ask for relevant information.  
3 However, the Court would not be fulfilling its mission to  
4 secure the just, speedy, and inexpensive determination of this  
5 litigation if it gives plaintiffs everything they ask for.

6 A good example is plaintiffs' request for regulatory  
7 information from not only the FDA, but numerous other  
8 regulatory bodies around the world. It is hard to dispute  
9 that all work product related to the investigation of  
10 Valsartan contamination is relevant. Nevertheless, leaning on  
11 its experience and common sense, it is apparent that a lot of  
12 this discovery will be repetitive. The Court, therefore, must  
13 reasonably limit plaintiffs' discovery in order to prevent  
14 duplicative, cumulative, and minimally important discovery.

15 As to defendants, a common theme running throughout  
16 their briefs is that "the deal has already been sealed" on the  
17 cause of the Valsartan contamination, when it started, the  
18 chemicals at issue, the exposure levels that may be harmful,  
19 and when tests existed to identify the contaminants at issue.  
20 The Court does not agree.

21 Certainly, there are working theories regarding these  
22 issues, but by no means have the issues been finally resolved  
23 to everyone's satisfaction. In any event, plaintiffs are not  
24 bound to the prevailing theories and have the right to reach  
25 their own conclusions after obtaining relevant discovery from

1 defendants.

2           Importantly, the Court will not necessarily bind  
3 plaintiffs to the prevailing theories and assumptions made by  
4 the FDA, and as noted today, plaintiffs are not agreeing to be  
5 so bound. Plaintiffs have a right to reach their own  
6 conclusions. It is no secret, and today plaintiffs  
7 acknowledged, that as the case progresses, plaintiffs may  
8 question the FDA's competency, biases, and motivations.

9           Another general comment the Court makes relates to  
10 Judge Kugler's justifiable comment that discovery should focus  
11 on the crux of the merits. This Court obviously agrees.  
12 However, by no means did Judge Kugler intend to foreclose  
13 plaintiffs from obtaining otherwise relevant discovery that  
14 does not fit squarely into defendants' notion of a critical  
15 issue.

16           The Court does not intend to give plaintiffs free  
17 reign to discovery, but on the other hand, the Court will not  
18 tie plaintiffs' hands at this early stage of the case, which  
19 will prevent plaintiffs from investigating whether the current  
20 working theories of liability and causation are viable.

21           The Court adds the comment that it disagrees with and  
22 rejects any notion that the parties have not had sufficient  
23 time to meet and confer about the discovery issues in dispute.  
24 From the outset of the case, plaintiffs have urged defendants  
25 to meet in person to hammer out discovery issues, but

1 generally, plaintiffs faced resistance from defendants.

2 In fact, as a last resort, on November 7, 2019, the  
3 Court was compelled to order defendants to meet in person with  
4 plaintiffs. Further, plaintiffs' document request was served  
5 on August 31, 2019; therefore, defendants have had two months'  
6 notice of what plaintiffs requested.

7 In addition, the parties have been on notice of the  
8 specific macro issues in dispute no later than the Court's  
9 October 22, 2019 order. Therefore, the Court will not defer  
10 its decision on any relevant issue on account of the fact  
11 defendants want more time to meet and confer.

12 Last, the Court makes it clear that it is deciding  
13 the party's discovery disputes on the present record. If  
14 material new facts are raised that could not previously have  
15 been known, the parties may make a new application to the  
16 Court. Since most of the Court's rulings weigh discretionary  
17 factors, for the most part, the Court's rulings are without  
18 prejudice.

19 Moving on to the macro issues in dispute, the Court  
20 will first address the issues raised by plaintiffs and then  
21 proceed to defendants' issues. For the most part, the Court  
22 will give the parties general rulings on broad topics. The  
23 more granular issues will be addressed and decided on  
24 December 11, 2019, after the parties have had additional meet  
25 and confer sessions.

1           The first issue the Court will address is plaintiffs'  
2 request to strike all of defendants' boilerplate objections to  
3 their document requests. Plaintiffs referred to the  
4 objections filed by ZHP, Teva, Mylan, Aurobindo, and Torrent.  
5 Defendants argue the issue is moot because revised objections  
6 have been served, except for Mylan.

7           As a general matter, the Court agrees defendants  
8 initially served boilerplate objections. To say this is  
9 disappointing is an understatement. Given the caliber and  
10 experience of defense counsel and their law firms, one would  
11 think defendants would know better. This is especially true  
12 since the Court put defendants on notice of its disdain for  
13 boilerplate objections.

14           It is not hard for the Court to decide defendants'  
15 initial objections were improper. The harder question is what  
16 to do about it. The fact that except for Mylan, defendants  
17 served revised and updated objections is of no moment. The  
18 objections were served too late for plaintiffs to address them  
19 and for the Court to have a meaningful opportunity to rule on  
20 their merits.

21           While the Court would be fully justified in striking  
22 all of defendants' objections to plaintiffs' document  
23 requests, it will not do this. One, the Court's paramount  
24 concern is to make sure the case is decided on the merits, not  
25 procedural irregularities.

1           Two, the Court unfortunately recognizes it is not  
2 easy to change a defense culture that has built up over the  
3 years, but, however, this has to and will change.

4           Three, plaintiffs do not have complete clean hands.  
5 As defendants point out, the purpose of ordering core  
6 discovery was to get in plaintiffs' hands early in the case  
7 key information to enable plaintiffs to focus and narrow their  
8 discovery requests.

9           For the most part, plaintiffs did not do this, but  
10 instead served general and overbroad requests. While  
11 defendants' boilerplate objections were not appropriate, many  
12 of plaintiffs' document requests were facially inappropriate.

13           Rather than striking defendants' objections, the  
14 Court will leave defendants with a stern warning: In the  
15 future, the Court will not permit boilerplate objections and  
16 resistance to meaningful meet and confer sessions. Defendants  
17 are on notice that if this occurs in the future, their  
18 objections will be stricken and/or company representatives  
19 will be ordered to informally meet with plaintiffs. The Court  
20 is confident that in the future, only appropriate objections  
21 will be served and it will not see resistance to meaningful  
22 meet and confer sessions.

23           The second issue to be addressed by the Court is the  
24 manufacturing facilities that must respond to discovery.

25           Defendants want to limit discovery to only the API

1 facilities that made Valsartan that was recalled. In  
2 defendants' papers, they argue they also want to hold off on  
3 discovery regarding the finished dose manufacturing facilities  
4 until plaintiffs' document requests are served, albeit this  
5 position may have changed during oral argument.

6 Plaintiffs want discovery from every entity and  
7 manufacturing facility in the Valsartan distribution chain; in  
8 other words, as plaintiffs write, "Every facility with any  
9 role for Valsartan."

10 Starting with defendants' API manufacturing  
11 facilities, the Court rules that every facility that  
12 manufactured Valsartan API that was sold in the United States  
13 is a proper subject of discovery and not just those facilities  
14 that manufactured Valsartan that was recalled.

15 The reason is because it is not clear that only  
16 recalled Valsartan is at issue in the case. The recalled  
17 Valsartan presumably contained contaminants that were  
18 detected. Plaintiffs are arguing that the defendants'  
19 Valsartan may have been contaminated, even though there are no  
20 available, as of yet, confirmatory tests. At the end of the  
21 day, it may be clear when Valsartan contamination started and  
22 what facilities the Valsartan came from. This is not known at  
23 the moment. Discovery directed to all of defendants'  
24 manufacturing facilities that sold Valsartan in the United  
25 States is the only way for plaintiffs to learn the answers to

1 these key questions.

2           The Court adds that the specific documents each API  
3 manufacturing facility must produce remains to be decided,  
4 however, a good start is defendants' testing results,  
5 regulatory inspection reports and warning letters.

6           The Court also adds it does not expect the discovery  
7 to produced by the finished dose manufacturers to be as  
8 extensive as that produced by the API manufacturers.

9           As to the finished dose manufacturers, the Court  
10 rules that all of defendants' finished dose manufacturing  
11 facilities that made finished dose Valsartan that was sold in  
12 the United States is a proper subject of discovery.

13           Even if these facilities did not cause the  
14 contamination, a fact not yet confirmed, plaintiffs are  
15 arguing these facilities had an independent duty to  
16 investigate and discover the contamination. In this regard,  
17 plaintiffs need to find out if these facilities followed  
18 current good manufacturing procedures or practices.  
19 Plaintiffs are entitled to find out if these facilities had  
20 actual or constructive notice of the contaminated Valsartan  
21 API.

22           One plainly relevant topic of discovery is whether  
23 the finished dose manufacturers did or should have conducted  
24 tests to detect NDMA and NDEA. Plaintiffs argue defendants  
25 have a quality assurance obligation with regard to its API

1 suppliers' processes and finished product. Plaintiffs are  
2 entitled to discover what steps the finished dose  
3 manufacturers took in this regard and whether they knew or  
4 should have known about problems with their API suppliers'  
5 tests and processes.

6           For the same reasons, discovery directed to all of  
7 defendants' API manufacturing facilities that made Valsartan  
8 API sold in the United States are relevant for discovery  
9 purposes and not just the facilities that made the recalled  
10 lots. All of defendants' finished dose manufacturing  
11 facilities that sold product in the United States are  
12 relevant.

13           In order to foster productive meet and confer  
14 sessions, within one week and to the extent not already done,  
15 the Court orders the API and finished dose manufacturing  
16 defendants to identify each of their facilities that will be  
17 subject to discovery.

18           As to the specific documents the finished dose  
19 manufacturing facilities must produce, that will be decided by  
20 December 11, however, to be clear, the Court rules that  
21 defendants' finished dose manufacturing facilities that sold  
22 product in the United States are not off limits for discovery.  
23 At a minimum, these facilities must produce API testing  
24 results, inspection reports, and communications regarding  
25 potential or actual nitrosamine contamination. As to other



1 downstream facilities such as bottlers, repackagers, or  
2 labelers, these discovery issues will be addressed in January.

3           The third issue to be addressed is plaintiffs'  
4 request for discovery regarding other products using the same  
5 manufacturing processes, solvents and testing as those for  
6 Valsartan API. In other words, plaintiffs want discovery  
7 regarding other sartans, even though only Valsartan is  
8 currently at issue thus far in the case. For several reasons,  
9 plaintiffs' request for this discovery is denied, except for  
10 one caveat. First, even though other sartans may be similar  
11 to Valsartan, only Valsartan is at issue in the case at the  
12 present time. The discovery directed to Valsartan will  
13 undoubtedly be extensive. The Court is skeptical that any  
14 materially relevant information will be gleaned from  
15 non-Valsartan discovery that will not be learned from the  
16 Valsartan discovery.

17           Thus, the burden and expense of the non-Valsartan  
18 discovery is disproportional to its importance and relevance.  
19 The same is true for other processes using the same solvents  
20 at issue in this case.

21           Two, pending before the MDL panel is plaintiffs'  
22 application to expand the scope of this MDL to include other  
23 sartans. The panel should weigh in on the issue before the  
24 Court effectively makes other sartans part of the case.

25           Three, until the panel tells this Court otherwise,

1 the Court wants to keep the focus of the case on the  
2 penultimate Valsartan contamination issue. Discovery directed  
3 to other sartans' processes, testing and solvents will divert  
4 the parties' resources and attention away from the core issues  
5 in dispute.

6 As mentioned, there is one caveat to the Court's  
7 ruling cutting off plaintiffs' discovery directed to other  
8 sartans. Because of the importance of the issue and the  
9 closeness of the chemical structure of the different sartans,  
10 the Court will direct defendants to produce all documents  
11 reflecting the presence of any nitrosamine in any sartan  
12 product made prior to July 2018. This includes not only  
13 documents involving Valsartan, but other sartans, such as  
14 losartan, irbesartan, olmesartan and candesartan.

15 The fourth issue to be addressed is plaintiffs'  
16 requests for the dates, distribution lists, and preservation  
17 instructions in defendants' litigation hold letters for  
18 e-mails. Plaintiffs' request for this information is granted  
19 in part and denied in part. The Court relies on its  
20 discussion in *Major Tours*, 2009, Westlaw, 2413631, District of  
21 New Jersey, August 4, 2009, for the applicable law. There,  
22 the Court held that as a general matter, litigation hold  
23 letters are not discoverable unless there is a good faith  
24 basis to believe spoliation occurred.

25 The Court agrees now with what it said then. The

1 Court does not find that plaintiffs have as yet made a case  
2 that spoliation occurred in this case. The Court carefully  
3 reviewed plaintiffs' master Complaints and identified the  
4 instances where plaintiff cited to actual or potential  
5 destruction of documents. In those instances, however, they  
6 occurred long before July 2018 when defendants could  
7 reasonably foresee litigation.

8 Without the reasonable foreseeability of litigation,  
9 there was no duty to preserve documents under the common law  
10 and, therefore, no spoliation. Plaintiffs did not cite to or  
11 rely on any regulatory requirement to support their spoliation  
12 argument.

13 Despite the fact that defendants do not have to  
14 produce their hold letters or e-mails, they do have to  
15 identify all recipients of the hold letters or e-mails and  
16 when they were sent. As plaintiffs argue, these objective  
17 facts are relevant to the identification of knowledgeable  
18 witnesses and custodians and is not privileged or protected  
19 work product. To avoid any confusion or unnecessary disputes  
20 in the future, the Court wants to make one point clear, that  
21 is, that although defendants do not have to produce copies of  
22 their actual letters or e-mails, plaintiff may address  
23 preservation issues with defendants' deponents. Plaintiffs  
24 are entitled to know whether a witness received a hold request  
25 and what he or she did to preserve relevant information. This

1 topic is not privileged or work product and is not off limits  
2 at defendants' depositions. Last, the Court declines  
3 plaintiffs' request to review defendants' hold letters in  
4 camera.

5 Now that the Court has addressed the four issues  
6 raised in plaintiffs' opening brief, the Court will turn to  
7 the eight issues raised in defendants' opening brief. The  
8 first issue to be addressed is plaintiffs' request for foreign  
9 regulatory documents. Unfortunately, plaintiffs do not  
10 identify the specific regulatory bodies from whom they request  
11 documents, nor the specific documents they request.

12 Plaintiffs ask for all documents regarding the  
13 Valsartan recall, foreign inspection reports, foreign  
14 regulatory submissions and other similar documents.  
15 Defendants argue plaintiffs' discovery should be limited to  
16 the FDA.

17 As to regulatory documents in general, the Court has  
18 already ordered fulsome discovery of FDA documents. This was  
19 covered in the Court's core discovery order, an order  
20 requiring plaintiffs be sent copies of all ongoing relevant  
21 communications between the FDA and defendants. Thus, in the  
22 Court's belief, it is likely that all non-privileged relevant  
23 FDA information regarding the issues in this case has or will  
24 get into plaintiffs' hands.

25 The Court finds that plaintiffs have not shown that

1   carte blanche regulatory discovery is needed. No persuasive  
2   evidence has been presented that hoards of relevant  
3   information is in foreign regulatory hands but not in the  
4   possession of the FDA.

5           The Court believes that if it opens the door wide to  
6   foreign regulatory discovery, the parties will get bogged down  
7   in duplicative discovery.

8           The Court does not rule, however, that all foreign  
9   regulatory discovery is off limits. Plaintiffs are entitled  
10   to materially relevant discovery that is not likely already in  
11   FDA's possession.

12           The Court, therefore, will order defendants to  
13   produce for each of the relevant facilities in the case,  
14   regulatory inspection reports, warning letters akin to what  
15   the FDA sends, 483-like documents, defendants' responses to  
16   these documents, root cause analyses and communications  
17   regarding potential or actual nitrosamine contamination prior  
18   to July 2008 that were sent to or received from any foreign  
19   regulatory body during the designated relevant time period.

20           The next issue defendants raise is plaintiffs'  
21   request for foreign sales marketing materials and agreements.  
22   This request is denied as the requested discovery is far  
23   afield from the material issues in the case.

24           The case involves sales of Valsartan in the United  
25   States and that is where the focus of plaintiffs' discovery

1 should and will be. Nonetheless, to the extent defendants  
2 have possession, custody, or control of documents from  
3 whatever source regarding unknown and unidentified testing  
4 peaks or general toxic impurities, the documents have to be  
5 produced. Plaintiffs' requests for all out-of-specification  
6 documents is too broad. This could involve issues such as the  
7 color, shape, texture, et cetera, of Valsartan, which is not  
8 relevant to the issues in the case.

9 Plaintiffs are directed to meet and confer with  
10 defendants on what they specifically want in this regard and  
11 raise disputes with the Court for the December 11th  
12 conference.

13 The next issue raised by defendants is the extent of  
14 discovery regarding each applicable defendants' finished dose  
15 manufacturing process. The Court has already discussed this  
16 issue and has nothing to add.

17 The fourth issue raised by defendants relates to what  
18 testing documents have to be produced. Although this is  
19 obviously one of the most important issues in the case, the  
20 plaintiffs are hamstrung in their discovery efforts, so they  
21 say, because they do not know the types of tests defendants  
22 conducted.

23 Clearly, plaintiffs are entitled to obtain discovery  
24 regarding any test that could identify the presence of  
25 nitrosamine contamination, such as NMBA and NDEA. The parties

1   apparently concede chromatography testing is relevant, but  
2   there may be other relevant tests. Defendants, therefore, and  
3   to the extent not already done, will be ordered to identify  
4   the types and purposes of the tests they ran at the subject  
5   facilities and to meet and confer with plaintiffs regarding  
6   the test results to be produced.

7           Disputes will be addressed on December 11. For the  
8   reasons already discussed, this ruling not only applies to API  
9   manufacturers but also to finished dose manufacturers. The  
10   parties should keep in mind that the facilities at issue are  
11   those that made products sold in the United States.

12           As to bioequivalence testing, this testing is  
13   relevant to the master economic loss claims and whether the  
14   purchasers got what they paid for. The testing is also  
15   relevant to whether defendants were or should have been aware  
16   of quality control issues, thus, bioequivalence testing shall  
17   be produced. Disputes regarding what testing should be  
18   produced, if any, should be raised in time to be addressed at  
19   the December 11 conference.

20           In order to avoid potential disputes, testing and  
21   results regarding other carcinogens, general toxic impurities  
22   or residual solvents in the Valsartan is relevant.

23           It would be anomalous to require defendants to  
24   produce test results revealing actual or potential NMBA or  
25   NDEA contamination, but not to reveal other similar toxic

1 contaminants. Albeit, one would think if this information  
2 existed, it would have already been turned over to the FDA.

3 The next issue to be addressed is the scope of health  
4 risk discovery. Defendants will be ordered to produce all  
5 documents, communications, and studies, et cetera, regarding  
6 the health effects of exposure to Valsartan contaminated with  
7 nitrosamines. Plaintiffs' request for health effect discovery  
8 regarding non-contaminated Valsartan is denied.

9 The next issue to be addressed is the relevant  
10 timeframe for general custodial searches. This is not an easy  
11 issue to decide, as both sides makes valid points. The Court  
12 ultimately concludes that it will not order the extensive time  
13 period plaintiff requests for general custodial searches.  
14 However, this does not foreclose plaintiffs from asking for  
15 earlier, discrete, and identifiable categories of documents or  
16 individual documents. To the extent plaintiffs and defendants  
17 cannot work out their issues, the Court will entertain the  
18 parties' discovery dispute and for good cause shown will order  
19 the production of earlier documents.

20 As to the relevant time period for general custodial  
21 searches, the Court will use the earliest date defendants  
22 proposed plus one year, starting from January 1. These dates  
23 are as follows: ZHP, January 1, 2010; Mylan, January 1, 2011;  
24 Teva, January 1, 2012; Torrent, January 1, 2013; Aurolife,  
25 January 1, 2012.



1           To repeat, the Court understands there are likely  
2 relevant older documents, but these will not be searched for  
3 until plaintiffs make a showing of good cause to produce  
4 discrete and identifiable documents or categories of  
5 documents.

6           As to Issues 7 and 8 in the Court's October 22nd,  
7 2019 order, the parties have advised the Court that these  
8 issues are not in dispute, except the Court notes for the  
9 record a clarification that if a defendant has otherwise  
10 translated a document in the normal course of business and not  
11 just for litigation purposes, it will be produced by the  
12 defendants.

13           That completes the Court's oral opinion to be  
14 confirmed in an order to be entered. Counsel, if there are  
15 any other issues you want to address, I'll address them, but  
16 we can adjourn and head over to courtroom 4D to meet with  
17 Judge Kugler.

18           For the good of the order, plaintiffs, any other  
19 issues to address?

20           MR. SLATER: Nothing, Your Honor. We thank you for  
21 your hard work on this.

22           THE COURT: Thanks.  
23 Defendants?

24           MR. GOLDBERG: Nothing, Your Honor. Thank you.

25           THE COURT: We're adjourned.

1           See you in courtroom 4D.

2           THE DEPUTY CLERK: All rise.

3           (2:55 p.m.)

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6           I certify that the foregoing is a correct transcript  
7 from the record of proceedings in the above-entitled matter.

8

9           /S/ Karen Friedlander, CRR, RMR  
10          Court Reporter/Transcriber

11

12          11-21-19  
13          Date

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